

### REMARKS

This Application has been carefully reviewed in light of the Office Action mailed April 4, 2008. At the time of the Office Action, Claims 1-15, 19 and 20 were pending in this Application. Claims 11-15, 19 and 20 were rejected. Claim 11 has been amended to further define various features of Applicant's invention. Claims 16-18 were previously cancelled without prejudice or disclaimer and Claims 1-10 were previously withdrawn due to an election/restriction requirement. Applicant respectfully requests reconsideration and favorable action in this case.

#### **Rejections under 35 U.S.C. § 112**

##### *Written Description*

Claim 11 was rejected by the Examiner under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner argues that the specification fails to disclose "forming a suspension consisting of a subject's autologous stem cells in a soluble medium." The exact process need not be described because it is known in the art. (*See* MPEP §2163(II)(A)(2). An applicant need not disclose in detail, and preferably omits, that which is conventional or well known in the art.) For example, the Examiner's own cited art, U.S. Patent No. 6,497,875 issued to J. Michael Sorrell et al. ("*Sorrell*"), indicates that antibodies markers for human mesenchymal stem cells are known. (Col. 13, lines 18-20.) The use of antibodies in cell sorting, *e.g.* via fluorescence activated cell sorters (FACS), is well known. Thus at least on method of forming a suspension of stem cells in a soluble medium is readily apparent; the cells may be sorted by FACS using cell-specific antibodies, then suspended in a medium. Other methods of sorting stem cells known to the art are also encompassed by Claim 11. Accordingly, Applicant respectfully requests full allowance of Claim 11 as amended.

##### *Indefiniteness*

Claims 11-15, 19 and 20 stand rejected by the Examiner under 35 U.S.C. §112, second paragraph, as being indefinite and failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant amends Claim 11 to

overcome these rejections and respectfully request full allowance of Claims 11-15, 19 and 20 as amended.

Specifically, the Examiner has rejected the step of “forming a suspension of a subject’s autologous stem cells and a soluble medium” as confusing because the Examiner is not sure how and from what tissue source such stem cells are obtained. Applicant asserts that the stem cells may be obtained by any manner known in the art from any source known to be suitable. At least one suitable source is identified in the Examiner’s own cited art, Sorrell.

The Examiner also rejected Claim 11 because it is allegedly not clear whether the stem cells are isolated or not. Claim 11 has been amended to recite isolated stem cells. Methods for isolating stem cells are also known in the art.

Finally, the Examiner has rejected Claim 11 because the “dispersing the suspension” step is allegedly confusing. Applicant has amended Claim 11 to indicate the role of the nozzle in this dispersion step.

### **Rejections under 35 U.S.C. §103**

Claims 11-15, 19 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,479,052 issued to Julian M. Marshall et al. (“*Marshall*”) or “Aerosolization of Epiderman Cells with Fibrin Glue for the Epithelialization of Porcine Wounds with Unfavorable Topography,” *Plastic Surgery and the Cryopreservation Laboratory*, by Meir Cohen et al. (“*Cohen*”) and U.S. Patent No. 6,497,875 issued to J. Michael Sorrell et al. (“*Sorrell*”). Applicant respectfully traverses and submits that Marshall does not render Claims 11-15, 19 and 20 obvious.

In order to establish a prima facie case of obviousness, the references cited by the Examiner must disclose all claimed limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Even if each limitation is disclosed in a combination of references, however, a claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int’l. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). Rather, the Examiner must identify an apparent reason to combine the known elements in the fashion claimed. *Id.* “Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must

be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.*, citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Finally, the reason must be free of the distortion caused by hindsight bias and may not rely on ex post reasoning. *KSR*, 127 S.Ct. at 1742. In addition, evidence that such a combination was uniquely challenging or difficult tends to show that a claim was not obvious. *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc. and Mattel, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007), citing *KSR*, 127 S.Ct. at 1741.

Applicant has amended Claim 11 to recite that “the forming the suspension and dispersing steps occur after, but within hours of the initial formation of the area of skin lacking normal, healthy skin.” (See Specification at p. 10, lines 6-9.) This limitation is neither disclosed nor taught or suggested by the cited references. In particular, in Marshall, the suspension formation and dispersion steps were not performed until ten days after wound formation. (Col. 12, lines 10-59.) Marshall achieved results the authors considered satisfactory even with this delay; therefore there is no teaching or suggestion to administer cells with a shorter time of formation of an area of skin lacking normal, healthy skin. Additionally, Marshall does not teach or suggest the use of stem cells. Marshall achieved results the authors deemed satisfactory without stem cells, which are more difficult to harvest than the keratinocytes used by Marshall. Accordingly, there is no motivation to use stem cells in the methods disclosed by Marshall.

Cohen similarly fails to disclose, teach or suggest the steps of Claim 11, as amended. In particular, even assuming, which Applicant does not concede, that all steps of Claim 11 are present in Cohen, the reference says nothing regarding the timing element of Claim 11. In particular, it appears that the forming the suspension step in Cohen as identified by the Examiner takes place before the formation of an area of skin lacking normal, healthy skin. (See p. 1208, Col. 1 and p. 1210 at particularly “Cell Suspension Preparation” and “Recipient Full-Thickness Wounds.”) In any event, it is not at all clear when the dispersing step, as identified by the Examiner, takes place in relation to the “forming the suspension step” as identified by the Examiner. (See pp. 1210-1211, at particularly “Cell Suspension Preparation” and “Aerosolization.”) Further, Cohen discloses only the use of a suspension of autologous skin cells that include keratinocytes, to which healing is attributed. (See p. 1213

at “Discussion.” Cohen achieved results the authors deemed satisfactory without stem cells, which are more difficult to harvest than a mix of autologous skin cells or keratinocytes. Accordingly, there is no motivation to use stem cells in the methods disclosed by Cohen.

The Examiner appears to cite Sorrell solely for its disclosure of the existence of stem cells. The Examiner has provided no reason why one would bother to combine the methods of Sorrell or any other stem cells isolation methods with the disclosures of Marshall and Cohen. As Applicant has explained above, the authors of Marshall and Cohen were satisfied with the results obtained using keratinocytes, which are easier to obtain than isolated stem cells. Accordingly, Applicant submits that the Examiner, by the arguments presented in the most recent Office Action, has at most merely shown that elements of Claim 11 exist in difference references (which Applicant does not admit). The Examiner has failed to provide any logical reason, lacking hindsight, why these elements would be combined to produce the method of Claim 11.

**CONCLUSION**

Applicant has now made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. Applicant respectfully requests reconsideration of Claims 11-15; 19 and 20 as amended.

Applicant encloses a Petition for a two-month extension of time with this response. The Commissioner is hereby authorized to charge the \$230.00 extension fee and any other necessary fees or credit any overpayment to Deposit Account No. 50-2148 of Baker Botts L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicant's attorney at 512.322.2580.

Respectfully submitted,  
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Date: September 2, 2008

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